DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

October 31, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Fred Donoho
Owner
Northern Beef Products, Inc.
625 E. 8th Street
Greeley, Colorado 80631

Ref. #: DEN-01-5

Dear Mr. Donoho:

Food and Drug Administration Investigator, Eric S. Myskowski, inspected your operation located in Greeley, CO. The inspection confirmed a heifer purchased and sold by you on July 24, 2000 through (XXXXXXXXXXXX) for slaughter for human food to (XXXXXXXX) was in violation of section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

USDA analysis of tissue samples collected from that animal disclosed the presence of sulfamethazine residues of 20.0 parts per million (ppm) in the liver and 14.0 ppm in the muscle. A tolerance of 0.1 ppm has been established for residues of sulfamethazine in the edible tissues of cattle in Title 21 Code of Federal Regulations Part 556.670 (21 CFR 556.670). The presence of this drug in this animal causes the food to be adulterated.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animal. As such, you share the responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. implementing a system to identify the animals you purchase with records to establish traceability to the source of the animal;

2. implementing a system to determine from the source of the animal whether the animal has been medicated and with what drug(s); and

3. if the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

Thomas A. Allison
District Director

cc: Mr. Ronald K. Jones
D.V.M.
Boulder District Manager
USDA/FSIS
665 S. Broadway, Suite B
Boulder, CO 80303

(XXX)